

a pulse generator [[sanctioned by government authority for implantation in a patient together with electrode means to treat said disorder by stimulation of a selected cranial nerve of the patient with]] capable of generating a predetermined sequence of electrical [[impulses from said pulse generator]] pulses, and

at least one electrode electrically coupled to the pulse generator, said electrode being implanted in the patient's body and coupled to a vagus nerve of the patient [[applied to the selected cranial nerve]] at a location in a range from about two to about three inches above or below the patient's diaphragm, for alleviating symptoms of the movement disorder in the patient.

23. (presently amended) The [[apparatus]] system of claim 22, wherein said pulse generator is programmable to enable physician programming of [[the electrical and timing]] a plurality of parameters defining [[of]] said sequence of electrical [[impulses]] pulses.

24. (presently amended) The [[apparatus]] system of claim 22, wherein the [[selected cranial nerve is the vagus nerve, and said electrode means comprises]] at least one [[nerve]] electrode [[for implantation on]] is attached to the patient's vagus nerve for direct stimulation thereof [[at said location]].

25. (presently amended) The [[apparatus]] system of claim 24, wherein said at least one electrode [[means]] comprises a pair of [[nerve]] electrodes for implantation [[of]] on a respective one of [[said pair on]] the left and right branches of the patient's vagus nerve for direct [[bilateral]] stimulation thereof at said location.

26. (presently amended) The [[apparatus]] system of claim 22, wherein said at least one electrode [[means comprises at least one electrode for implantation internally]] is attached to a portion of the patient's [[nervous system]] body remote from the [[selected cranial]] vagus nerve to indirectly stimulate the vagus nerve [[selected cranial nerve in the vicinity of said location]].

27. (presently amended) The [[apparatus]] system of claim 22, further including
a sensor for sensing the patient's body movement, and

a sense signal analysis circuit [[associated with the pulse generator]] for analyzing a signal produced by [[a]] the sensor, for determining [[in response to movement of the patient to assess]] whether the patient's movement is [[random, uncoordinated and]] an involuntary movement characteristic of the movement disorder being treated, and[[, if it is,]] for activating the pulse generator to stimulate the vagus nerve if the movement is determined to be such an involuntary movement [[selected cranial nerve in the vicinity of said location]].

28. (presently amended) The [[apparatus]] system of claim 22, including activation means associated with the pulse generator for enabling patient activation of the pulse generator to stimulate the vagus nerve [[selected cranial nerve in the vicinity of said location]].

29. (presently amended) Apparatus for treating patients suffering from movement disorder, comprising

a pulse generator [[approved by a government agency of competent authority to be implanted with]] capable of generating an electrical signal; and

at least one [[interconnected nerve]] electrode implanted in a patient to treat said movement disorder by applying [[a programmed sequence of]] the electrical [[impulses]] signal generated by said pulse generator to [[a branch of]] the patient's vagus nerve, [[via said electrode]] wherein said at least one electrode is coupled to said pulse generator and is attached to [[implanted on]] said vagus nerve at a location in a range from about two to about three inches above or below the patient's diaphragm, for relieving symptoms of the movement disorder in the patient.

30. (presently amended) The apparatus of claim 29, wherein said pulse generator is adapted to be programmed by a physician to provide electrical [[and timing]] parameters [[of said impulses]] defining said electrical signal.

31. (presently amended) The apparatus of claim 29, further comprising an electrical lead coupled to said at least one electrode and having [[wherein said electrode means has]] a length sufficient to enable said [[nerve]] at least one electrode to be [[implanted on]] attached to said vagus nerve at said location.

32. (new) The apparatus of claim 29, further comprising a programming unit coupled to said pulse generator for programming a plurality of parameters to define said electrical signal.

33. (new) The apparatus of claim 32, wherein said pulse generator is implanted in the body of the patient and said programming unit is external to the patient's body and wirelessly coupled to said pulse generator.

34. (new) A system for treating a patient having a movement disorder comprising:
a pulse generator capable of generating an electrical signal;
at least one implanted electrode, coupled to the pulse generator and attached to a vagus nerve of the patient at a location below the patient's diaphragm, for applying said electrical signal to said vagus nerve to treat said movement disorder; and
a programming unit for programming said pulse generator to define said electrical signal.

35. (new) The system of claim 34 wherein said pulse generator is implanted in the body of the patient.

36. (new) The system of claim 34 wherein said pulse generator is external to the body of the patient and is wirelessly coupled to said at least one electrode.

37. (new) The system of claim 34 wherein said programming unit is capable of programming at least one parameter selected from the group consisting of current magnitude, frequency, pulse width, on-time and off-time.

REMARKS

In the present Office Action, claims 22-31 have been considered. Original claims 1-21 have been deleted, and claims 29-31 were added by preliminary amendment. In the present amendment, each of claims 22-31 has been amended and new claims 32-37 have been added. After entry of the amendment, claims 22-37 remain for consideration.

Claims 22-31 stand rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-21 of US. Patent No. 6,622,038. Applicants acknowledge the provisional rejection. However, because no claim has been indicated as allowable, a terminal disclaimer is premature at present. Applicants will timely file a terminal disclaimer upon indication of allowable claims properly rejected on this basis.

Claims 22-31 further stand rejected as anticipated under 35 U.S.C. §102(b) by US 5,025,807 to Zabara. According to the Examiner:

Col. 7, lines 7+ teach electrode placement along any part of the vagus nerve. The specific location of the electrodes in applicant's claims is considered to be intended use, not a structural limitation.

Office Action of 11/25/05, at 3 lines 9-11.


While the '807 patent does note that it is "theoretically possible" to couple an electrode "anywhere along the length of the vagus nerve" ('807 patent at col. 7 lines 7-9), the only location actually disclosed in the '807 patent for electrode placement on the vagus nerve is at the cervical (i.e., neck) area. Moreover, the specific comment referred to by the Examiner at col. 7 lines 7-11 merely teaches that the electrodes be located "below the inferior cardiac nerve," and does not teach or suggest locations in the diaphragm area.

Applicants have amended independent claims 22 and 29 to recite a system comprising an implanted electrode that is coupled to the vagus nerve at a particular location, i.e., "at a location in a range from about two to about three inches above or below the patient's diaphragm." The claims as amended recite a structural element that is neither disclosed nor suggested by the cited reference. Newly added independent claim 34 recites an electrode that is "attached to a vagus nerve of the patient at a location below the patient's diaphragm." This structural element is likewise not disclosed or suggested by the cited reference.

Applicants submit that the claims as presently presented are allowable over the cited reference. Accordingly, it is respectfully requested that the proposed Amendment be entered, the claims reconsidered, and that early notice of allowability be provided.

02/27/06
Date

Respectfully submitted,



Timothy L. Scott
Reg. No. 37,931

Cyberonics, Inc.
100 Cyberonics Blvd.
Houston, Texas 77058

Phone: (281) 727-2652
Fax: (281) 853-2505

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with
the United States Postal Service with sufficient postage as first class
mail in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on 02/27/06
(Date)

Dianne Mangrum
(Name of person making deposit)

Dianne Mangrum
(Signature)